

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1058964	(X3) Date Survey Completed 11/21/2025
Name of Provider or Supplier Pediatrics Plus	Street Address, City, State 3401 Magnolia Cove, Monroe, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Validation survey was conducted at SFMG Pediatrics - Magnolia Cove - CLIA ID # 19D1058964 on November 21, 2025. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel records and interview with personnel, the laboratory failed to follow the established policy to ensure the laboratory director or technical consultant performed competency assessments for hematology testing personnel for two (2) of two (2) personnel reviewed in 2025. Findings: 1. Review of the laboratory's "Personnel Competency Testing Program" policy revealed "CLIA '88 requires the laboratory to document the competency of all testing personnel before they begin working, every 6 months during the first year of employment and annually thereafter. An individual serving as Lab Director or Technical Consultant may perform this documentation". 2. Review of the personnel records in 2025 revealed the office manager performed the competency assessments for the following two (2) of two (2) testing personnel: a) Testing Personnel 1 b) Testing Personnel 2 3. In interview on November 21, 2025 at 11:30 am, the technical consultant confirmed the competency assessments were performed by the office manager.</p>
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory supplies had not exceeded their expiration dates in 2025.

Findings: 1. Observation by surveyor during the laboratory tour on November 21, 2025 at 09:30 am revealed the following expired items on two (2) of two (2) phlebotomy trays located in the laboratory: a) BD Vacutainer SST blood collection tubes; Lot 4326313; Expiration 10/31/25; Quantity (1) b) BD Vacutainer K2E blood collection tubes; Lot 4166428; Expiration 09/30/25; Quantity (11) c) BD Vacutainer K2E blood collection tubes; Lot 4137092; Expiration 08/31/25; Quantity (9) 2. In interview with personnel on November 21, 2025 at 9:45 am, Testing Personnel 1 and 2 confirmed the vacutainer tubes were expired and in place for patient testing.

D5805

TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the laboratory's patient test reports and reference ranges as well as interview with personnel, the laboratory failed to ensure the reference range documentation in the laboratory information system (LIS) for complete blood count (CBC) testing was the appropriate normal ranges for three (3) of three (3) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on November 21, 2025 at 9:30 am revealed the laboratory utilizes the Horiba ABX Micros 60 hematology analyzer for complete blood count (CBC) testing. 2. In interview on November 21, 2025 at 11:58 am, the office manager stated the laboratory was acquired by different ownership in April 2025 and the current ownership utilizes the laboratory information system (LIS) EPIC. 3. Review of the laboratory's reference range documented in LIS EPIC revealed the following ranges were utilized: a) Patient final report normal ranges: * White Blood Cell (WBC): 3.5 - 10 $10^3/mm^3$ * Red Blood Cell (RBC): 3.8 - 5.8 $10^6/mm^3$ * Hemoglobin (HGB): 11.0 - 16.5 g/dL * Hematocrit (HCT): 35 - 50 % * Platelet (PLT): 150 - 450 $10^3/mm^3$ b) Laboratory Information System (LIS) EPIC * White Blood Cell (WBC): 4.6 - 10.2 $100/uL$ * Red Blood Cell (RBC): 4.04 - 5.40 M/uL * Hemoglobin (HGB): 12.0 - 16.0 g/dL * Hematocrit (HCT): 37.0 - 47.0 % * Platelet (PLT): 130 - 400 $1000 u/l$ 4. Review of a random selection of the following three (3) of three (3) patients revealed the different references ranges in the LIS and final report: a) Patient Medical # 1818234 b) Patient Medical # 4221941 c) Patient Medical # 1060660 5. In interview

	<p>on November 21, 2025 at 11:58 am, the technical consultant stated upon review of the LIS documentation for reference ranges that the appropriate ranges were not used for the patient final report.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and records as well as interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5417.</p>
D6026	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)</p> <p>(e)(8) Ensure that reports of test results include pertinent information required for interpretation;</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and records, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel records, and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures for assessing personnel competency were maintained. Refer to D5209.</p>
D6036	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory policy and records and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Refer to D5417. 2. The laboratory failed to ensure patient normal ranges and the reference range documentation in the laboratory information system (LIS) for complete blood count (CBC) testing was the appropriate normal ranges for three (3) of three (3) patients reviewed. Refer to D5805.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, personnel records, and interview with personnel, the Technical Consultant failed to perform complete competency assessment procedures. Refer to D5209.